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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,974	06/04/2001	Mathew A. Von Wronski	2238-7	6852

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EXAMINER

AUDET, MAURY A

ART UNIT PAPER NUMBER

1654

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/871,974

**Applicant(s)**

VON WRONSKI ET AL.

**Examiner**

Maury Audet

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,23-36 and 49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33 is/are allowed.
- 6) ☒ Claim(s) 1, 23-32, 34-36, and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Claim Rejections - 35 USC § 112 1<sup>st</sup> Scope of Enablement***

The rejection of claims 1, 23-32, 34-36, and 49, under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (see previous two office actions). The specification, while being *enabling for the peptide TKPPR or an analogue which contains therein "TKPPR"* (e.g. GTKPPR) (which specifically binds to NP-1 or cells that express NP-1 with avidity that is equal to or greater than TKPPR) as monomer A, does not reasonably provide enablement for any analogue of TKPPR (e.g. less than "TKPPR") as monomer A, in the invention's composition or method of ultrasound imaging. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant has argued that the description of a single TKPPR analogue of "GTKPPR" enables any and all TKPPR analogues, which specifically binds to NP-1 or cells that express NP-1 with avidity that is equal to or greater than TKPPR. Applicant also argues that determining which TKPPR analogues confer the function above would not pose an undue burden on one of skill in the art (e.g. deletions/substitutions therein). Applicant has also provided a declaration to the same. Applicant's arguments have been considered but are not found persuasive.

Applicant has provided no enabling disclosure or argument indicating which residues of "TKPPR" must be present to allow binding of such analogue for the desired effect. Absent the former, figuring out which analogues (including substitutions/

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deletions), would pose an undue burden on one of ordinary skill in the art. It is suggested that Applicant amend the claims to claim an analogue which must comprise at least those amino acid residues of TKPPR to confer the desired effect of binding to NP-1 or cells that express NP-1 with avidity that is equal to or greater than TKPPR. Absent such claim language, one of ordinary skill in the art would not be apprised of which analogues would function to meet the claimed invention, or be able to determine the same without an undue burden.

Thus, there are an innumerable number of potential peptide fragments, and amino acid substitutions (conservative or non-conservative), that could chemically alter/be synthesized into the peptide TKPPR; however, Applicant has not clearly shown any of these "analogues" (other than a single analogue which still contains "TKPPR"). Specifically, Applicant has not described which residues of "TKPPR" must be present in the analogue to allow it to function/bind to NP-1 or cells that express NP-1 with avidity that is equal to or greater than TKPPR. Absent

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***Allowable Subject Matter***

The compound of claim 33 is not reasonably taught or suggested by the prior art of record.

***Conclusion***

Claim 33 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA 8/04/05



CHRISTOPHER R. TATE  
PRIMARY EXAMINER